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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/081,713	02/21/2002	Carlos R. Plata-Salaman	ORT-1583	1258

27777 7590 09/12/2003
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EXAMINER

SPIVACK, PHYLLIS G

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 09/12/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/081,713

Applicant(s)

Plata-Salaman et al.

Examiner

Phyllis G. Spivack

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on May 29, 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 7, 8 6) ☐ Other:

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Applicants' Request for Continued Examination (RCE) filed May 29, 2003, Paper No. 6, is acknowledged and has been accepted.

Claims 1-25 remain under consideration.

Two Information Disclosure Statements filed May 29, 2003 and June 9, 2003, respectively, Paper Nos. 7 and 8, are further acknowledged and have been reviewed to the extent each reference has been provided and is a proper citation on a U.S. Patent. The various co-pending and related applications listed in the Information Disclosure Statement filed June 9, 2003 have been reviewed.

Claims 1, 5, 11, 20 and 23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

Parenthetical subject matter renders the claims in which they appear indefinite. It is unclear whether or not claim limitations are intended.

Claims 1-25 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claims are directed to preventing or treating any anxiety disorder comprising administering a compound or an enantiomer of Formula I, II, Ia, Iia, Ib or IIb. The specification provides no support for preventing or treating anxiety disorders.

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Attention is directed to In re Wands, 8 USPQ2d 1400 where the court set forth factors to consider when assessing whether or not a disclosure would require undue experimentation. These factors are:

- 1) the quantity of experimentation necessary
- 2) the amount of direction or guidance provided
- 3) the presence or absence of working examples
- 4) the nature of the invention
- 5) the state of the art
- 6) the relative skill of those in the art
- 7) the predictability of the art and
- 8) the breadth of the claims.

The instant specification fails to provide guidance that would allow the skilled artisan background sufficient to practice the instant invention without resorting to undue experimentation in view of further discussion below.

The nature of the invention, state of the prior art, relative skill of those in the art and the predictability of the art

The claimed invention relates to prevention or treatment of any anxiety disorder.

The relative skill of those in the art is generally that of a Ph.D or M.D.

Each particular anxiety disorder has its own specific characteristics and etiology. The broad recitation “preventing or treating anxiety disorder” is inclusive of many conditions that

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presently have no established successful therapies. A successful treatment modality for one particular anxiety disorder does not presage success with another anxiety disorder.

The breadth of the claims

The claims are very broad and inclusive of many disorders of diverse etiology.

The amount of direction or guidance provided and the presence or absence of working examples

There are no working examples.

The quantity of experimentation necessary

Applicants have failed to provide guidance as to which particular compound would be preferred for preventing or treating the various anxiety disorders that are encompassed in the claim language. The skilled artisan would expect the interaction of a particular compound in the prevention or treatment of a particular anxiety disorder to be very specific and highly unpredictable absent a clear understanding of the structural and biochemical basis for each agent. The instant specification sets forth no such understanding. No direction is provided to distinguish therapy among the various anxiety disorders. Absent reasonable *a priori* expectations of success for using a particular chemotherapeutic agent to treat any particular anxiety disorder, one skilled in the psychiatric art would have to test extensively many compounds to discover which particular disorder responds to a particular compound. Since each prospective embodiment, as well as future embodiments as the art progresses, would have to be empirically tested, undue

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experimentation would be required to practice the invention as it is claimed in its current scope.

The specification provides inadequate guidance to do otherwise.

No claim is allowed.

Bossinger et al., U.S. Patents 3,313,692 and 3,248,418, are cited to show compounds of the present invention for sedation, calming or tranquilization. Choi et al., U.S. Patent 6,103,759, is cited to show the enantiomers of the present invention are known in the prior art.

Any inquiry concerning this communication should be directed to Phyllis Spivack at telephone number 703-308-4703.

September 11, 2003

A handwritten signature in black ink that reads "Phyllis Spivack". The signature is written in a cursive, flowing style.

**PHYLLIS SPIVACK
PRIMARY EXAMINER**